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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,460	12/05/2000	Karl Kolter	51007	4443

7590 10/02/2002

Messrs. Keil & Weinkauff
1101 Connecticut Ave., N.W.
Washington, DC 20036

EXAMINER

DEWITTY, ROBERT M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,460

Applicant(s)

KOLTER ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9, 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 are pending in the instant application. Claims 1-6, 10 and 14 are withdrawn from further consideration. Claim 10 depends on claim 1 and should have been included with group I. The response to the restriction filed 2/26/02 is not signed. Applicant is requested to acknowledge the election and finality of the restriction made in the last office action. Acknowledgement is made of Applicant's response filed 7/27/02.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 7-9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (U.S. Pat. No. 5,098,714), further in view of Cherukuri et al. (U.S. Pat. No. 4,931,293) and Patell (U.S. Pat. No. 4,916,161).

Wright teaches an osmotic device with an exterior coat for delivery of steroids over a prolonged period of time. The coat of the osmotic device, in addition to other ingredients such as steroids, can be encompassed with an outer taste-mask such as hydroxypropylmethylcellulose (col. 7, lines 15-18). Wright teaches that previously, steroids were delivered by the prior art in a dose unprotected from the environment of the gastrointestinal tract, with little consideration of the steroid's effects (col. 1, lines 39-44).

Cherukuri teaches the combination of polyvinyl acetate and emulsifiers which produces coatings. These coatings protect food acids (or flavors) from conditions such

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as pH changes, reactive agents and the like (col. 5, lines 10-16). The coating is useful for a variety of core materials, including drug and other particular materials for protection or for taste masking (col. 6, lines 27-31).

As shown in the patent to Patell, the unpleasant taste of ibuprofen is well documented, and efforts to overcome this bad taste have been numerous. Patell teaches a method of taste masking for ibuprofen involving the use of hydroxypropyl methylcellulose phthalate (abstract and col. 1, lines 4-11).

Motivation to utilize a polyvinyl acetate and emulsifier composition with the coating of Wright would have arisen to allow the delivery of the steroids to the gastrointestinal tract in a protected form. A taste-masking composition, such as hydroxymethylcellulose, in the coating would have been used as taught by Wright. The application of the taste masking method to a drug such as ibuprofen would have been within the interest and skill of one in the art attempting to overcome the bad taste of ibuprofen.

Response to Arguments

2. Based on Applicant's arguments with regards to the 35 U.S.C. 102 rejection namely that Cherukuri does not teach a hydrophilic additive, the rejection has been withdrawn.

3. Regarding the rejection under 35 U.S.C. 103(a), Applicant asserts that the invention of Cherukuri is ineffective for its intended purpose. Applicant also asserts that Khankari, which furthers the invention of Cherukuri, would not achieve the results of the

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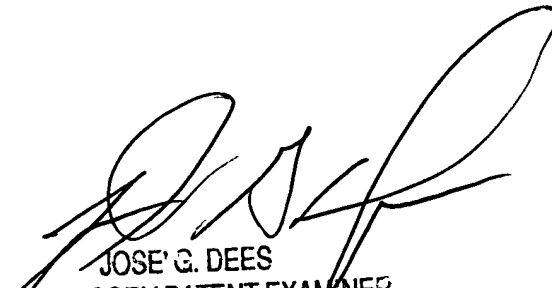
instant invention. Based on Applicant's arguments, the previous rejection has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
October 1, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
